

WHAT IS CLAIMED IS:

- 1 1. An intravascular guidewire comprising
- 2 a) an elongated member having a proximal portion and a
- 3 distal portion and being formed at least in part of a superelastic alloy
- 4 consisting essentially of about 30 to about 52% titanium, about 38 to
- 5 about 52% nickel and up to 20% additional alloying elements selected
- 6 from the group consisting of iron, cobalt, platinum, palladium, copper
- 7 and vanadium, said alloy part having an austenite phase which has a
- 8 final transformation temperature below about 45° C., which
- 9 transforms to a martensite phase upon the application of stress and
- 10 which has been thermomechanically formed in a procedure which
- 11 includes a final cold working followed by a heat treatment at a
- 12 temperature between about 450° to about 600° C. while applying
- 13 tension to the cold worked elongated member; and
- 14 b) torquing means on the proximal end of the elongated
- 15 member.

- 1 2. The guidewire of claim 1 wherein the alloy contains one or more
- 2 additional alloying elements selected from the group consisting of iron,
- 3 cobalt, platinum and palladium in amounts of up to about 3%.

1 3. The guidewire of claim 1 wherein the alloy contains one or more
2 additional alloying elements selected from the group consisting of copper in
3 amounts of up to 12% and vanadium in amounts of up to about 10%.

1 4. The guidewire of claim 1 wherein the temperature of the heat
2 treatment is between about 475° and about 550° C.

1 5. The guidewire of claim 1 wherein the superelastic portion has a
2 straight memory at a temperature less than about 45° C.

1 6. The guidewire of claim 1 wherein the final cold worked alloy
2 part is mechanically straightened before the heat treatment.

1 7. A superelastic alloy body having an austenite phase which is
2 stable at a desired operating temperature and which will transform to
3 martensite phase upon the application thereto of stress, exhibiting a
4 recoverable strain of at least about 4% upon the stress induced
5 transformation of the austenite phase to martensite phase and having been
6 formed by thermomechanical processing which includes a final cold working
7 about 10 to about 75% and a memory imparting heat treatment at a
8 temperature between about 475° and about 600° C.

1 8. The body of claim 7 wherein the strain of the body during the
2 stress induced transformation of the austenite phase to the martensite phase
3 is within the range of about 2% to about 8%.

1 9. The body of claim 7 wherein the austenite-to-martensite
2 transformation occurs at a relatively constant stress above about 50 ksi.

1 10. The body of claim 7 wherein the austenite-to-martensite
2 transformation occurs at a relatively constant stress above about 70 ksi.

1 11. The body of claim 7 wherein a distal portion thereof has a
2 plurality of sections which have progressively smaller cross-sections in the
3 distal direction.

1 12. The body of claim 7 further comprising a flexible member
2 disposed about the superelastic distal portion thereof.

1 13. The body of claim 12 wherein the flexible member is a helical
2 coil with a rounded plug on the distal end thereof.

1 14. The body of claim 6 wherein tension is applied to the elongated
2 body while being subjected to the memory imparting heat treatment.

1 15. The body of claim 6 wherein the body is subjected to
2 mechanical straightening between the cold working and heat treating steps.

1 16. A fixed-wire balloon angioplasty catheter comprising:

2 a) an elongated catheter body with an inner lumen
3 extending therein;

4 b) an inflatable balloon on the distal extremity of the
5 catheter body and having an interior in fluid communication with the
6 inner lumen of the catheter body; and

7 c) a guiding member which is disposed at least in part
8 within the interior of the inflatable balloon and which is formed at
9 least in part of a superelastic alloy body having an austenite phase
10 which is stable at a desired operating temperature and which will
11 transform to martensite phase upon the application thereto of stress,
12 exhibiting a recoverable strain of at least about 4% upon the stress
13 induced transformation of the austenite phase to martensite phase and
14 having been formed by a thermomechanical processing which includes
15 a final cold working of about 10 to about 75% and then a memory
16 imparting heat treatment at a temperature between about 450° and
17 about 600° C while tension is applied thereto.

1 17. The fixed wire balloon angioplasty catheter of claim 17 wherein
2 the thermomechanical processing includes a mechanical straightening
3 between the cold working and heat treating.

1 18. A method of forming a superelastic elongated member being in
2 an austenite phase which is stable at temperatures less than about 45° C.;
3 providing an elongated member formed of an alloy
4 consisting essentially of about 30 to about 52% titanium, about
5 38 to about 52% nickel and up to a total of about 20% of one
6 or more additional alloying elements selected from the group
7 consisting of iron, cobalt, chromium, platinum, palladium,
8 copper, vanadium, zirconium, hafnium and niobium;
9 subjecting the elongated member to thermomechanical
10 processing which includes a final cold working of about 10 to
11 about 75% and a heat treatment at a temperature between
12 about 450° and about 600° C. while subjecting the elongated
13 member to a tension of up to about 50% of the room
14 temperature tensile strength.

1 19. The method of claim 18 wherein the elongated member is
2 subjected to mechanical straightening after the final cold working but before
3 the heat treatment.

1 20. The method of claim 18 wherein the heat treating temperature
2 is between about 475° and about 550° C.

1 21. The method of claim 18 wherein the final cold-worked number
2 is heat treated for about 0.5 to about 60 minutes.

1 22. An elongated tubular body suitable for use within a human body
2 which has a cylindrical wall defining an inner lumen therein, which is formed
3 of a superelastic alloy consisting essentially of about 30 to about 52%
4 titanium, about 38 to 52% nickel, and to about 20% of one or more
5 elements selected from the group consisting of iron, cobalt, chromium,
6 platinum, palladium, copper, vanadium, zirconium, hafnium and niobium in a
7 stable austenite phase which will transform to martensite phase upon the
8 application of stress, which will exhibit a recoverable strain of at least about
9 4% from the application of stress which transforms the austenite phase to
10 the martensite phase and which has been fabricated by a thermomechanical
11 processing which includes a final cold working of about 10 to about 75%
12 and then a memory imparting heat treatment at a temperature of about 450°
13 to about 600° C.

1 23. The tubular body of claim 22 wherein the stress level at which
2 the austenite phase transforms to the martensite phase is above 50 ksi.

1 24. The tubular body of claim 22 wherein the austenite-to-
2 martensite transformation occurs at a relatively constant yield stress above
3 about 70 ksi.

1 25. The tubular body of claim 22 wherein the alloy contains at least
2 one element selected from the group consisting of up to about 20% copper
3 and up to about 10% vanadium.

1 26. The tubular body of claim 22 wherein the alloy contains at least
2 one element selected from the group consisting of iron, cobalt, palladium and
3 platinum in amounts up to about 3%.

1 27. The tubular body of claim 24 having an outer diameter of about
2 0.006 to about 0.05 inch and a wall thickness of about 0.001 to about
3 0.004 inch.

1 28. A method of forming a superelastic elongated member having a
2 straight memory comprising subjecting an elongated member having a
3 composition consisting of a predominant amount of NiTi intermetallic
4 constituent to thermomechanical processing which includes a final cold
5 working of about 10 to about 75% and a heat treatment at a temperature

6 between about 450° and about 600° C. while subjecting the cold worked
7 elongated member to sufficient tension to ensure a straight memory.

1 29. The method of claim 28 wherein the elongated member is
2 formed of an alloy consisting essentially of about 30 to about 52% titanium,
3 about 38 to about 52% nickel and up to a total of about 10% of one or more
4 additional alloying elements selected from the group consisting of iron,
5 cobalt, chromium, platinum, palladium, copper, vanadium, zirconium,
6 hafnium and niobium.

1 30. The method of claim 29 wherein the elongated member is in the
2 austenite phase.

1 31. The method of claim 29 wherein the heat treatment is at a
2 temperature between about 475° to about 550° C.

1 32. The method of claim 29 wherein the elongated member is
2 mechanically straightened after the final cold working and before the heat
3 treating.